REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 25-30 and 32-39 were under consideration. Claims 1-24, 31, and 40 have been cancelled without prejudice. Claims 41-53 are newly added in this application. Applicant reserves the right to pursue the subject matter of the cancelled claims in a continuing application.

Claims 25-30 and 32-36 have been clarified to recite "rodent" rather than "animal" or "non-human animal." Claim 26 has been clarified to recite "increases in bone pathology comprising vulnerability of bone tissue, bone resorption or delay in bone growth" rather than "changes in bone pathology comprising vulnerability of bone tissue, change of bone morphology or delay in bone growth." Claims 41-53 have been added and mirror the pending claims and recite rat instead of rodent. Support can be found on page 15, line 19 - page 16, line 7 and page 30, lines 9-28. The amendments to claims 25-30 and 32-36 are made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter has been added by these amendments.

The Examiner is thanked for withdrawing the objections to the specification and claims and for withdrawing the rejections under double patenting and 35 U.S.C. §101.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

II. THE OBJECTION TO CLAIMS 26, 32, AND 34 IS OVERCOME

Claims 26, 32, and 34 were objected to because the specification allegedly failed to make clear what the differences are between "any vulnerability of bone tissue" and "changes in bone morphology." It was also allegedly unclear how a decrease in "any vulnerability of bone tissue" is pathological. The claims have been clarified to recite "*increases* in bone pathology comprising vulnerability of bone tissue, *bone resorption* or delay in bone growth" rather than

"changes in bone pathology comprising vulnerability of bone tissue, change of bone morphology or delay in bone growth." An increase in bone resorption indicates bone mineral dissolution or bone mass decrease. One of skill in the art would recognize that an increase in bone resorption is clearly pathological. Reconsideration and withdrawal of the objections is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH, ARE OVERCOME

A. The Rejection Under 35 U.S.C. §112, First Paragraph With Regards to Claims 25-30 and 32-39 is Overcome

Claims 25-30 and 32-39 are rejected under 35 U.S.C. §112, first paragraph because the specification allegedly lacks enablement. The Office Action of April 26, 2006 (hereinafter "the Office Action") contends that the specification "does not reasonably provide enablement for any non-human animal that over expresses regucalcin and shows bone pathology, a method for using said animal in a screening method for preventative and therapeutic agents, and a therapeutic or preventative agent." Although Applicant does not agree with the Office Action, in the interest of expediting prosecution, claims 25-30 and 32-39 now recite "A transgenic rodent model..."

For the reasons that follow, Applicant respectfully urges that that the application, as filed, is adequately enabled. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

As the Office Action admits, the specification does provide adequate guidance and evidence for the production of the claimed transgenic rat model that overexpresses regucalcin and shows bone pathology, a method for using the transgenic rat model in a screening method for preventative and therapeutic agents, and a therapeutic or preventative agent. The specification, therefore, is also enabling for all claims directed to a transgenic rodent model.

The MPEP indicates in Section 2164.02 that "compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed." Furthermore, the MPEP states that "because only an enabling disclosure is required, applicant need not describe all actual embodiments." Applicant respectfully points out that working examples presented in the specification, along with the description, would allow one skilled in the art to practice the full scope of the claimed transgenic rodent model without undue experimentation. MPEP, §2164.01(a); see also In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (factors such as the level of one of ordinary skill in the art and the level of predictability in the art

must be considered when determining whether experimentation is undue). The specification, as filed, explains that "the base sequence of regucalcin cDNA of the mouse liver... by comparison with regucalcin cDNA of rat liver... [has] 94% homology (*see, e.g.*, page 4, line 12). The Applicant submits that the techniques used to generate and use a transgenic rodent model are predictable and well-known to one of ordinary skill in this art and that one of ordinary skill would be able to practice the claimed invention without undue experimentation.

The Examiner's attention is respectfully directed to some case law regarding the first paragraph of Section 112. It is a well known principle that claims must be read in light of the specification. See In re Marosi, 710 F.2d 799 (Fed. Cir. 1983). Furthermore, it has been determined that the claims need not be limited to preferred embodiments in the specification. It is improper, according to In re Goffe, 191 U.S.P.Q. 429, 431 (CCPA 1976), to limit the claims of an application to the specific examples in the specification under the guise of lack of enablement:

> To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials . . . would not serve the constitutional purpose of promoting, progress in the useful arts.

It is urged that the subject matter in the claims is not broader than the enabling disclosure. Applicant respectfully submits that the claims are more than adequately supported by the specification. There is no particular number of examples which make specific claim language adequate or enabled. Indeed, enablement is not even related to the number of examples in the specification. In In re Borkowski, 164 U.S.P.Q. 642, 646 (CCPA 1972), the court stated:

> There is no magical relation between the number of representative examples and breadth of the claims . . . the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated'.

Moreover, "the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 USC §112". Staehelin v. Secher, 24 U.S.P.Q.2d 1513, 1516 (B.P.A.I. 1992). Indeed, a specification need not disclose–and best omits—that which is well known in the art. In re Buchner, 929 F2d 660 (Fed. Cir. 1991).

The Examiner is also respectfully reminded that it has been held that the specification must be accepted as enabling of the invention under 35 U.S.C. §112, unless doubt as to the truth/accuracy of the statements made with the specification is raised:

> It is incumbent upon the Patent Office . . . to explain why it doubts the truth or accuracy of any statements in supporting disclosure and to backup assertions of its own with acceptable evidence or reasoning which is inconsistent with the contended statements.

In re Marzocchi, 169 U.S.P.Q. 367 (CCPA 1971).

Therefore, the specification provides guidance and enabling disclosure for the claimed transgenic rodent model and thus, for the full scope of claims 25-30 and 32-39.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, are respectfully requested.

B. Added Claims 41-53 are Enabled

As indicated in the Office Action, the specification is "enabling for a transgenic rat comprising a transgene comprising the rat regucalcin gene, wherein the rat overexpresses regucalcin, which causes a decrease in bone density, bone strength or bone thickness, and a method of using said transgenic rat in a screening method for preventative and therapeutic agents. Newly added claims 41-53 recite a transgenic rat model and a screening method wherein a test substance is administered to a transgenic rat model. Applicant respectfully requests allowance of the added claims, as the Office Action admits that the specification is enabling for the added claims.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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